PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 29/00 — A1

(11) International Publication Number: WO 99/59669

(43) International Publication Date: 25 November 1999 (25.11.99)

(21) International Application Number: PCT/US99/11084

(22) International Filing Date: 18 May 1999 (18.05.99)

(30) Priority Data:
60/085,896 18 May 1998 (18.05.98) US

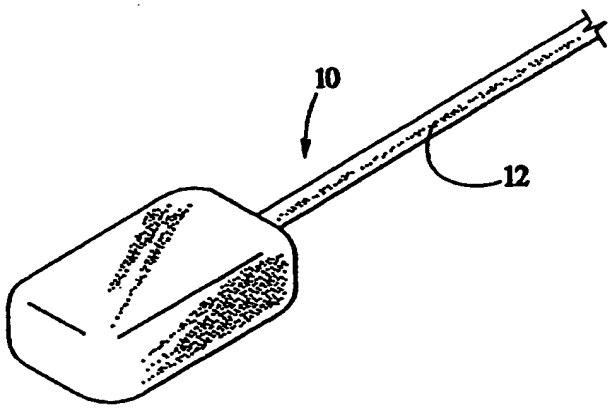
(71)(72) Applicant and Inventor: BRYAN, Vincent, E., Jr. [US/US]; Suite 110, 9655 S.E. 36th Street, Mercer Island, WA 98040 (US).

(74) Agent: PARKHURST, Todd, S.; Hill & Simpson, Sears Tower, 85th floor, 233 South Wacker Drive, Chicago, IL 60606 (US).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: BALLOON JACK



(57) Abstract

The invention relates to an inflatable balloon catheter (10) called a balloon jack, which serves to distract vertebral bodies (17, 18) or other anatomical structure at the site of an implant or other surgical procedure. The device is an alternative to a standard intervertebral body separator. It is designed to minimize damage to the cortical endplates during distraction. The balloon jack (10) is fabricated from non-compliant polyethylene terephthalate (PET), commonly used in urology, and cardiology balloon catheters. In addition, the balloon jack (10) may be used to separate other structures including bone at locations throughout the body.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

SPECIFICATION

TITLE:

"BALLOON JACK"

FIELD OF THE INVENTION

This utility application claims domestic priority from U.S. Provisional Application Serial No. 60/085,896, filed May 18, 1998.

BACKGROUND OF THE INVENTION

This invention relates generally to separators for approximated bones, and more specifically relates to intervertebral body separators. The invention also relates to surgical procedures associated with the introduction of the balloon jack and the manner in which it is configured to relate to the surfaces upon which the jack will act.

The distraction or separation of vertebral bodies on either side of the disc space is undertaken to facilitate a surgical procedure between the two bones which is best undertaken when the space is enlarged. This applies also to other joints. Mechanical means of separating bones, in particular the vertebral bodies, usually utilizes firm, usually metal, surfaces which apply a mechanical load to the engaged bony surfaces, which in turn facilitates the separation of the two

interposed surfaces. Often times, however, the surface upon which the mechanical force is exerted is small, and frequently the bone surfaces not configured to the form of the metallic surface acting on it. Consequently, as the distractor force is increased, mechanical disruption of the bony surface occurs leading to uneven and compromised bone surfaces. This becomes especially important during implant procedures wherein the maintenance of the integrity of the bone surface is essential to the proper performance of the functional implant device to be inserted.

In the past, Cloward and Smith-Robinson popularized anterior surgical spinal approaches, and, more recently, Ray and others have developed means to distract the intervertebral disc spaces mechanically for the insertion of bone grafts, fusion cages, hydrogel nuclei replacement, etcetera. In every instance, mechanical devices have been utilized, including metallic spreaders, metallic shims, wedges, and, in the case of Kaspar, distracters attached to posts inserted in the approximating bone. In every instance, bone damage on the surface or in the softer central portion of the bone itself may result if the distraction force on a relatively small area exceeds the inherent strength of the bone at that area.

It is the primary aim of the present invention to provide a means of distraction which will exert the forces required for such distraction over a larger surface, and in a manner wherein that force can be configured, during the period of distraction, to mate with the bone surface area.

It is another object to maintain such distraction, once the desired degree of distraction has been achieved without loss of separation over time.

It is another object to be able to introduce the means of distraction, i.e., the balloon, through a very small opening, to inflate it to a much larger size than the entry port, and to remove it through the same small opening without compromising surrounding tissue.

It is yet another object to achieve the pressures within the balloon necessary to fulfill the goal of distraction and have a means of determining what such pressures are at any given time and, thereby, to limit excessive pressures which might cause either failure of the balloon or deformation of the bony surface upon which it is acting.

Other objects and advantages of the invention will become apparent upon reading the following detailed description and upon reference to the drawings. Throughout the drawings, like reference numerals refer to like parts.

SUMMARY OF THE INVENTION

To accomplish these objects, the invention compromises an inflatable balloon made of non-compliant polyethylene terephthalate (PET) designed to distribute the force sufficient to provide the distraction in the intervertebral disc space or in whatever joint space it might be placed, such that separation of the opposing bony surfaces will take place as desired, although pressures on the bone will be below pressures that would lead to bony deformation. Thus, the

relationship of the size of the balloon to the insert space and the deformation pressure factor can be computed for any given joint space, and the balloon sized accordingly. The shape of the balloon is configured in a somewhat rectilinear or cubical fashion, though it is not limited to such. The non-compliant (PET) sides limit the expansion of the balloon except in those areas of the opposing bones with the sides of the balloon being of such length as to allow the balloon jack to be effective through the desired distraction range.

The stem assembly to the balloon must be of significant thickness to allow the pressure required to perform the distraction and to inflate the balloon to such pressures to be maintained without deformation of the stem. It is yet another object to provide a method of inserting the balloon jack through a narrow tube such as might be used in microsurgery or endoscopic surgery.

To accomplish these objectives, the invention comprises an inflatable balloon with attached catheter which serves to distract the vertebral bodies at the site of the implant. The insertable balloon catheter is preferably made of non-compliant polyethylene terephthalate (PET) and is fashioned in its shape and size in accordance with the requirements of load and surface area described above. Once inflated, the predetermined geometric shape conforms to the surrounding bony surfaces. Continued inflation initiates the distraction process to the desired degree.

To construct the balloon jack for any given application — as for

specifically the intervertebral disc space — information is obtained regarding the size, shape, and desired distraction of the vertebral bodies for a particular indication and then the balloon is fabricated to provide such distraction within the framework of the load limitations described above — i.e., the compressibility leading to deformation of the surrounding bony surfaces in that area. The length of the stem is determined by the surgical technique, such that the surgeon may inflate the balloon through the stem while the hands are well free of the wound area. It is important that the balloon, prior to insertion, be collapsible, and that its width together with that of the stem be of such size that it can be readily passed through the openings in the various tissue planes as well as through any canulus which may provide access to the desired location.

DETAILED DESCRIPTION

While initially described in connection with the preferred embodiment and procedure, it will be understood that it is not intended to limit the invention to this embodiment or procedure. On the contrary, it is intended to cover all alternatives, modifications and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an isometric view of the novel balloon jack in its deflated condition;

Figure 2 is an isometric view of the novel balloon jack in its inflated

condition;

Figure 3 is a fragmentary elevational view showing the balloon jack in its inflated, distracting condition between two vertebrae; and

Figure 4 is an isometric view of the enplaced balloon jack; adjacent vertebrae, the balloon jack stem and a pressure-supplying syringe.

DETAILED DESCRIPTION

Turning more specifically to the drawings, the deflated balloon jack 10 (and its attached stem 12) is shown in its inflated form in Figures 2-4 has been placed into an intervertebral disc space 20 located between adjacent vertebral bodies 17 and 18. The balloon jack can be inflated in the intervertebral disc space by liquid or gas delivered through a syringe 15 attached to the stem 12. Later, the balloon jack may be deflated and removed. Maintenance of the intervertebral disc space may be sustained by means of a known retractor (not shown) placed into the intervertebral disc space, the blades of which straddle the inflated balloon before inflation, thereby allowing distraction to be mechanically maintained following removal of the deflated balloon jack.

To encourage maximal distraction with minimal load applied to any given segment of the opposing bones, it is the intention of the design of the balloon jack to occupy the maximum area available between the opposing bones so as to spread the force over the maximum area, thereby decreasing bone deformation. It should be noted that the surface of the deflated balloon 10, when

expanded as shown in Figures 2-4, by the injection of a fluid from the syringe 15 through the stem 12, can, by the properties of the material, conform when under load to the anatomical shape of the opposing bony surfaces.

Though the material described in the description (PET) is essentially non-expansile, any other polymeric material possessing similar properties may be utilized in the manufacture of the balloon.

Claims:

1. An inflatable balloon catheter jack which serves as a jack when inflated to distract opposing bones in a joint space, the balloon jack being configurable as to size and shape such that the forces required to separate the opposing bones can be spread over a large surface area of the opposing bones when expanded to achieve the desired degree of expansion without causing damage or deformation to the opposing bone surfaces.

2. An inflatable balloon catheter jack according to Claim 1, wherein said balloon is fabricated from non-compliant polyethylene terephthalate (PET) material which may be collapsed or expanded to a predetermined size and shape.

3. An inflatable balloon catheter jack according to Claim 1, further including a stem attached to a syringe or other pressurizing system, the stem providing for the introduction of a fluid or gas to expand said balloon for purposes of distracting two opposing bony surfaces.

4. An inflatable balloon catheter according to Claim 1, wherein the inflated balloon has a rectilinear shape similar in shape and size available to the surgical area after the balloon has been surgically entered so as to allow maximum bony surface bearing of the applied distraction force over the greatest available area to accomplish distraction without bony deformation.

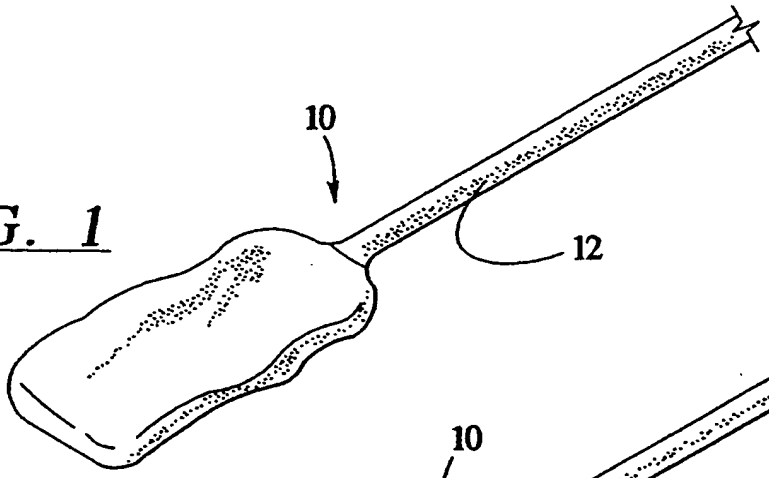


FIG. 1

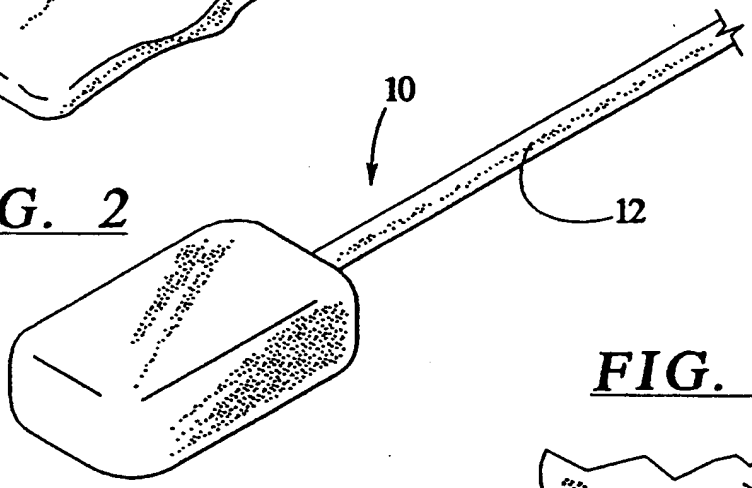


FIG. 2

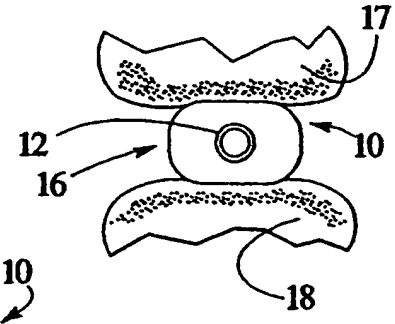


FIG. 3

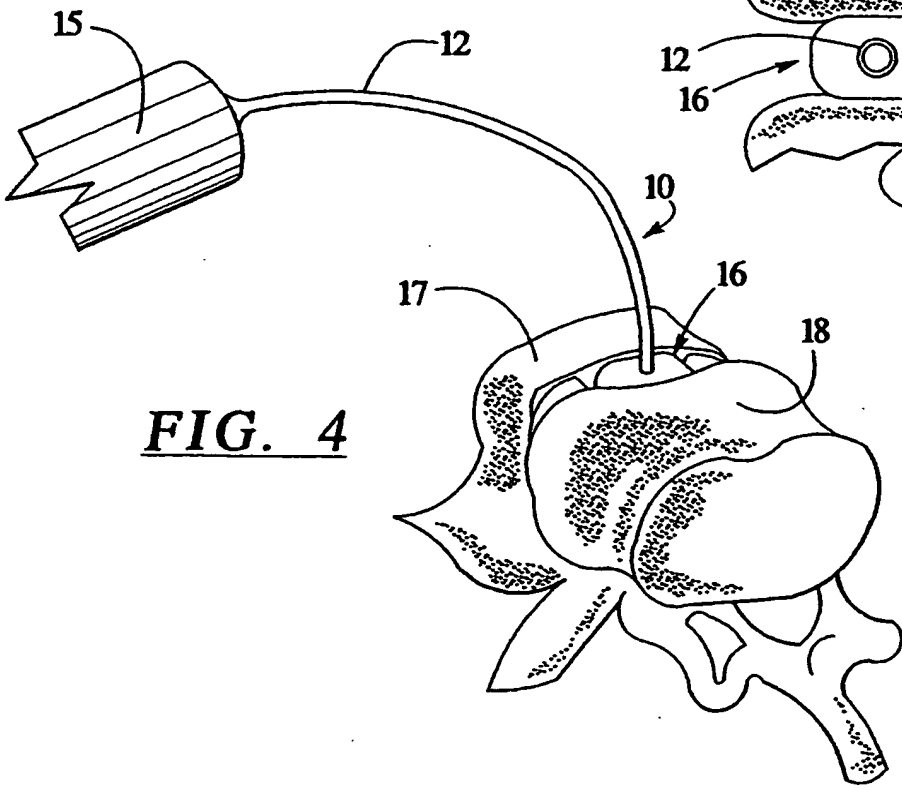


FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/11084

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00
US CL :604/96

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96, 97, 98; 606/192

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,021,043 A (BECKER et al) 04 June 1991, col. 6 lines 46-55.	1-4
X	US 5,169,386 A (BECKER et al) 08 December 1992, entire document.	1-4
X	US 5,645,560 A (CROCKER et al) 08 July 1997, col. 7 lines 46-59.	1-4
X, P	US 5,843,116 A (CROCKER et al) 01 December 1998, entire document.	1-4

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
30 JULY 1999

Date of mailing of the international search report
25 AUG 1999

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer
KEVIN C. SIRMONS

Telephone No. (703) 306-5410

Form PCT/ISA/210 (second sheet)(July 1992)*